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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/534,825	03/23/00	FRUDAKIS	T 210121.419C7

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EXAMINER	
HARRIS A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/534,825	Applicant(s) FRUDAKIS ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *4-16 and 21-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 17-20* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-3 and 17-20) in Paper No. 10 is acknowledged.

2. Claims 1-60 are pending.

Claims 4-16 and 21-60, drawn to non-elected inventions are withdrawn from examination.

Claims 1-3 and 17-20 are examined on the merits.

Priority

3. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. § 120. The Examiner has noted that the instant application claims priority to the continuation-in-part of 09/429,755, filed October 28, 1999, which is a continuation-in-part 09/289,198, filed April 9, 1999, which is a continuation-in-part of 09/062,451, filed April 17, 1998, which is a continuation-in-part of 08/991,789, filed December 11, 1997, which is a continuation-in-part of 08/838,762, filed April 9, 1997, which is a continuation-in-part of PCT/US97/00485, filed January 10, 1997, which is a continuation-in-part of 08/700,014, filed August 20, 1996, which is a continuation-in-part of 08/585,392, filed January 1, 1996. The limitations of SEQ. ID. NO: 292 (1851 base pairs) is disclosed in 08/991,789, filed December 11, 1997 and the limitations of SEQ ID NO:299 (329 amino acids) is

disclosed in 09/289,198, filed April 9, 1999. Thus, claims 1 and 2 containing the nucleic acid sequence will be granted priority to December 11, 1997. Claims 3 and 17-20 directed to polypeptides will be granted the priority date of April 9, 1999.

Information Disclosure Statement

4. The information disclosure statement filed October 23, 2000, Paper No. 7 lists a number of documents that were to be considered by the Examiner. However, not all of the documents were found in the instant application available for review. Hence, the listed documents "lined through" were not reviewed during examination and not considered. The Applicant is invited to submit the references for consideration

Drawings

5. The drawings are objected to because of reasons cited on attached form PTO 948 completed by draftsman. Correction is required.

Claim Objections

6. Claims 1-3, 17 and 18 objected to because of the following informalities:

a. claims 1-3 contain non-elected SEQ ID numbers not examined on the merits; b. claim 1(b) contains an underscore and c. claims 17(b)-(e) and 18(b)-(e), sections contain non-elected subject matter and references to claims (4, 11, 12 and 16) not examined on the merits. Correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is broadly drawn to an isolated polypeptide comprising at least an immunogenic portion of a protein, or a variant thereof encoded by a nucleotide sequence recited in SEQ ID NO: 292. Thus, all cited claims are broadly drawn to a genus of nucleic acid molecules that encompass a larger nucleic acid that contains portions of nucleic acid that encode the amino acid sequences of SEQ ID NO: 299 protein, immunogenic portion of the protein or variant thereof. The specification describes only the cDNA sequences of SEQ ID NO: 292. The specification does not describe any of the structural elements of a gene that would encode these actual DNA sequences of promoter and regulatory regions and introns, all defining elements of a "gene". The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural

features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides encoding the claimed polypeptides and variants thereof. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. The specification proposes to discover other members of the genus by using... There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed and no identifying characteristic or property of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

The specification further fails to identify and describe the 5' and 3' regulatory regions and untranslated regions essential to the function of the claimed invention, which are required since the claimed invention currently encompasses the gene. Therefore, the structure of these elements is not conventional in the art and those skilled in the art would therefore not recognize from the disclosure that applicant was in

possession of the genus of nucleic acid, including genes, comprising SEQ ID NO: 292 or fragments thereof.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific nucleotide sequences and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed. Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Likewise, the specification does not contain any disclosure of the function of a full-length open reading frame (ORF) that includes SEQ ID NO: 292. The genus of cDNAs including SEQ ID NO:292 is very large and members of the genus are variable because of the potentiality of the many different proteins they may encode. Therefore, many structurally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. One skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

9. Claims 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claimed invention. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim 17 is broadly drawn to "a pharmaceutical composition comprising a polypeptide..." and claim 18 is broadly drawn to "a vaccine, comprising a polypeptide...". The specification while being enabling for a composition comprising a polypeptide of claims 1-3 (specifically SEQ ID NO:299) and a pharmaceutically acceptable carrier, does not reasonably provide enablement for a "pharmaceutical composition" or a "vaccine" comprising these same components. Claims drawn to "pharmaceutical compositions" and "vaccines" are broadly interpreted to read on compositions effective for use as *in vivo* human therapeutics. The polypeptide of the invention is completely uncharacterized functionally. The mere fact that it seems to be expressed in cancerous tissues and associated with the development of breast cancer is not sufficient to establish that it plays a role in the pathology or etiology of breast tumors in these tissues. In the absence of an established role of the polypeptides in cancerous diseases of the breast it is impossible to predict what if any therapeutic effect the administration of the polypeptides would have for the treatment of breast disorders and cancer. The selection and development of such human therapeutics is art known to be highly unpredictable. The specification exemplifies no examples of the effective use of the polypeptides as a pharmacological agent. Accordingly, those skilled in the art cannot rely on this information to implement the processes of treating or preventing a breast cancer.

Furthermore, Ezzell (Journal of NIH Research 7:46-49, January 1995) reviews the current thinking in cancer vaccines and states that tumor immunologists are reluctant to place bets on which cancer vaccine approach will prove effective in the long run (see the entire document, particularly last paragraph) and further states that no one is very optimistic that a s single peptide will trigger an immune response strong enough to eradicate tumors or eve to prevent the late growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy (page 48, paragraph 6). One skilled in the art would not know how to use the claimed compositions as the component polypeptides were not known prior to the applicant's invention. SEQ ID NO: 299's function as a variant or immunogenic portion is not known and is not disclosed in the specification with the development of cancer. The specific association is not elucidated. None of the polypeptides and the polynucleotides that encode the polypeptides and portions and variants thereof that are claimed are known to be useful for the treatment or prevention of cancer. Therefore, due to the unpredictability of therapeutics and the absence of any evidence concerning the effectiveness of the claimed vaccines or pharmaceutical composition as a pharmacological agent, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use with a reasonable expectation of success, the invention commensurate in scope with this claim. The association provides no guidance as to how the instant polypeptides can be employed as therapeutic nor a basis to predict their efficacy. The applicant is advised to amend the claim to delete the recitation of "pharmaceutical".

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 is vague and indefinite in the recitation "...an immunogenic portion of a protein...". What defines a portion? Is it the amino terminus, carboxy terminus or several amino acids? Accordingly, it is impossible to determine the metes and the bounds of the claimed invention.

b. The recitation "...a variant thereof..." in claim 1 is vague and indefinite. It is not clear what is meant by the phrase. Thus the metes and the bounds of the claimed "...variant thereof is unclear.

c. The recitation "under moderately stringent conditions" in claim 1 is not clear. The metes and bounds of the claimed polynucleotides are unclear, in absence of limitations specifying specific stringency conditions.

Conclusion

12. Claims 1-3 and 17-20 are free of the art.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

(703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
September 24, 2001

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